

Memo

Date: January 21st, 2008

Subject: ASCO CPC/ACCC Meeting January 18 - January 19, Washington D.C.

From: J. Chris Nunnink

Dear Members,

This is a brief review of the recent Clinical Practice Committee Meeting and ACCC President's Retreat held in Washington D.C. on Friday and Saturday, January 18th and 19th. Overall, I felt that this meeting was similar to the previous meetings in that addressed several challenges forthcoming and some efforts on the legislative front to try to direct these changes in a more positive direction. Nevertheless, the challenges that we face over the next three to five years will certainly become more complex and more difficult. Thus, what I have elected to do is just provide an overview. Please refer to the ASCO and ACCC web sites to stay informed on the legislative and regulatory issues. Both organizations also provide regular email updates which you can subscribe to (ASCO's Cancer Policy Today and ACCC's This Week at ACCC).

MEDICARE REIMBURSEMENT

Overall, the balanced budget amendment of 1997 is still wreaking havoc. The balanced budget amendment as you know caps the cost of providing care using a formula based on the sustainable growth rate or SGR. The balanced budget amendment includes various services in addition to the professional fees provided to physicians and these include drugs (would account for approximately 11% and is clearly growing) imaging services and home care. Thus as a consequence of this physician reimbursement has decreased since we all have to share a piece of the pie and the pie does not grow but the non-physicians segment of "the pie" does. As you know, every year for the last several years, the SGR formula has resulted in a decrease in the Medicare conversion factor. Each year the government has tried to initiate a fix or at least freeze the conversion factor. We currently have a six-month "fix" – a 0.5 increase. Congress will need to address this again before June 30. The expected proposal is for an 18-month fix, and this will not be passed until later this year. In addition re-imbursement will most likely decrease for drugs and infusions because of changes in components of the relative value system.

OTHER MEDICARE ISSUES CMS is now organizing into 15 different geographical areas or Medicare Administrative Contractors (MACS). Medicare carriers (Part B) and fiscal intermediaries (Part A) will be consolidated into these MACs. The goal is for CMS to deal with fewer local directors so that standardized policy can be initiated (CMS has two defined routes for coverage either local or national).

In addition, CMS is utilizing new tools and rules to either review or refute new drugs, as well as reviewing previous FDA drugs. Moreover, it now will review drugs if these drugs are “novel, complex, or controversial; costly to the Medicare program; or subject to overutilization. The most contentious of these are the erythropoietin group of drugs. These ESA's are now being re-reviewed by CMS. This is very contentious issue since this is the first time that CMS is reviewing and changing coverage for a previously approved drug and not agreeing to proceed with FDA dictated recommendations. Also, it sets narrow clinical parameters around the course of treatment and dosing, and does not address specific situations such as transfused patients, and finally introduces administrative complexities and tiered care for privately insured versus Medicare patients. Thus, if you look at the Medicare regulations for administering ESA, the recommendations are not only more stringent than FDA guidelines had proposed, but they impose specific doses of the drug. Moreover, the FDA through ODAC will be reviewing the specific guidelines in the last few months and most likely change the guidelines referenced above. Thus this sets an interesting and novel precedent. Of the 300 or so reviews, this is the only review that proposes to make such stringent rule changes unilaterally and not in accord with recommendations based upon scientific review. They propose to make the rule changes based on their interpretation without input from an expert panel. This has broad ramifications for both ASCO as well as the AMA. The ESA rule sets a precedent that will affect every physician since these rules can be applied to all subspecialties and many other drugs. Thus, it is extremely important that AMA work together with ACSO and that we work with our delegates in the AMA to make sure that the government first and foremost follows its rules and secondly does not attempt to practice medicine with complete disregard for physicians input and adequate review of the literature. The CMS attitude mimics “managed care” models or as I prefer the “just say no” approach. CMS is also looking into Abarelix for Prostate cancer, chemotherapy for colon cancer, PET scans, and costs of clinical trials, as well as screening and anti emesis treatments. Also the FDA is having financial difficulties and it appears that the CMS is reviewing its fiduciary responsibility to the point where the autonomy of the physicians is being sacrificed. Clearly, ASCO’s Cancer Policy Today is an important way to stay up to date in this regard.

CMS is also setting up RACS or recovery audit contractors – or as Dr Hayes puts it “bounty hunters”. This began as a pilot program in three states (Florida, California, and New York) and will roll out to all states over the next 2 years. You must comply with audits by these RACS; ASCO asks that you inform them of the details if your practice is selected for audit.

Also, ASCO still does not have a seat on the RUC committee. Again, the RUC committee is the committee in charge of deciding how much is paid for the codes that we bill to CMS. ASCO will be

petitioning for a seat on the RUC (as it has for over 10 years). But, at least ACSO and the AMA are working together on issues such as that noted above and other issues to forge legislative fixes. This is certainly an encouraging sign and several people are leading the effort to build more bridges with the AMA. I would especially like to cite Dr. Barbara L. McAneny's effort in this regard. She is on the board of directors of ASCO and also is incredibly effective ASCO representative at the AMA. Creating more bridges with the AMA would help us work together on these important legislative issues.

CLINICAL TRIALS

Another topic of discussion at this meeting concerned clinical trials. This is actually a crisis. 60% of the drug company sponsored trials are now sent overseas. The legislative burden is increasing and the re-imbursment for clinical trials is decreasing. Thus, if you look at the cost of doing a clinical trial at the present time (certainly under the auspices of national cooperative groups) most practices lose money on clinical trial participation. Drug company sponsored trials are becoming more burdensome and re-imbursment is not keeping up with this. Some phase II and phase III trials are done jointly by the FDA and the drug company. A good example of a blended trial is NSABP trial B-40. These trials have the extra regulation requirements of federally sponsored trials – and the reimbursement is approximately 1/3rd of a industry sponsored trial. More cumbersome safety reports (i.e. some difficult to sort out since they may originate in North Korea for example) also increase the administrative burden (since any safety concerns need to be amended to the consent form or sent to active patients. Thus it appears that more practices are having a very difficult time affording clinical trials at the present time and most of these as noted above are being shipped overseas. Also legislation that assures our patients access to clinical trials does not cover patients in a self insured care plans. These self-insured plans do not have to cover clinical trials because of a specific exclusion – section 514 of ERISA - and this trumps state law. The only way to get these companies to do this is to ask the individual company to add this coverage to their employer's health plan. It would take national legislation to fix this. This I think does constitute a crisis since the basis for advancing excellent care for our patients relies heavily on clinical trials. I cite the problem without any specific answers. I think it is important for all of us to watch our costs closely and obviously cooperation will be crucial in maintaining this important mission.

OFF-LABEL DRUG USE

The off-label drug issue again has come up. The CMS again is making it more difficult to order off-label drugs. The issue becomes more difficult because of changes in the compendialisted in the original legislation. The USPDI, for one, no longer exists and is now Drug Points; it is still unclear as to whether CMS will accept Drug Points as a complete “replacement” for USPDI. ACCC and ASCO have been working together on this important issue. AHFS (American Hospital Formulary Service) has been

re-vitalized and a speaker from AHFS outlined their new processes for considering drugs for inclusion in that compendia. CMS has established a new policy for considering additional compendia; the application process is open now and NCCN is expected to apply for compendia status. However, orphan cancers will find it difficult to get coverage for new drugs. In my own efforts to try to institute a treatment for a metastatic thyroid cancer patient (a “orphan cancer”), for instance, the only option left to me was the standard option based upon studies 20 years old using toxic cisplatin and adriamycin. A new Phase I, Phase II study did not meet criteria for approval. A new phase I/II study for example showed excellent results in 6 of 8 patients with little toxicity; however, it is not covered and no Phase II studies are planned. The CMS recommendation was simply to contact the regional director. This in our area is Dr. Craig Haug. When contacted he did not feel that he could single handedly approve this and it would have to go through the routine process (i.e. we give it, it gets denied and then we appeal it – and stand a good chance of being denied). At the CPC meeting I was told that he did have the power to approve this. Thus, physicians now have a more difficult time with newer effective drugs when treating orphan cancers and there is no mechanism within CMS to deal with this.

ORAL THERAPIES, SPECIALTY PHARMACY

In addition, since oncologists are now facing significant reductions in revenue, practices in most areas of the country are implementing other services to make up for the reduction. Those services included imaging services as well as in-house pharmacies. These in-house pharmacies cover both Medicare part D as well as Medicare part B drugs. Specifically, oral chemotherapy has become somewhat of a contentious issue since it takes a great deal of time and effort to get these drugs approved and to work with the patients and potential toxicities, and there is no re-imburement for this work; thus special pharmacies have developed to offer their services. These pharmacies are supposed to check to make sure patients can get the drugs, bill for these, and also check compliance. It is not clear that they would help the increasingly underinsured patients (where staff has to file for funds from the various foundations to cover out of pocket costs). However, the costs are exorbitant and feedback is questionable. Two options to deal with this are to set up your own pharmacy, take the loss, or work with a specialty pharmacy. Several groups have found that by having an in-house pharmacy to dispense oral chemotherapy as well as anti-emetics and some antibiotics, as well as pain medications can be helpful and get therapy to pts in a timely manner and use the small profit to offset the extra administrative costs. One practice lost a great deal of money in this regard. Another practice gained and usually the expectation is that you need to write at least 20 prescriptions a day (for a practice of 5 or more physicians) to make this a reasonable option. Thus in the Northeast where physician practices are small, this may be a difficult option. In addition, at least in Vermont, since CON process is extremely difficult, very rarely do physicians have the opportunity to either add imaging or an in-house pharmacy.

SUMMARY

Thus, it appears that we will be facing several hardships and again this reinforces my desire to work through NNECOS since we provide local support to prevent the erosion of the excellent care we provide to patients. Maintaining the infrastructure in place so we can continue to do this is extremely important. We are facing challenges both from the regulatory side and from the clinical trials front, and diminished reimbursement. We will need all the energy at our disposal to work through these difficult times. I suspect the times will get worse rather than better. Again, I would strongly recommend that people go both to the NNECOS site, as well as the ASCO and ACCC web sites. I would encourage people to stay up to date with the local coverage policy news – Cancer Policy Today. These updates are extremely critical. Moreover, if any individual practices are having a difficult time, it would be important to address these through NNECOS so that these issues can come to light. It is often times simple issues in local offices that can change policy on a national level. Certainly the most important issue in my mind is access. The changes cited affect all of us. The answers will come from physician input in conjunction with our patients. The message can best be articulated through an organization that represents these entities – and NNECOS will certainly stay on task in this regard.